

**REMARKS**

Claims 1-44 are pending in the present application. Of these claims, claims 25-33 have been withdrawn from consideration by the Examiner. By virtue of this response, claim 2 has been cancelled and claims 1, 16, 17, 23, and 24 have been amended. No new matter has been added. Accordingly, claims 1, 3-24, and 35-44 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented.

***Withdrawal of Claims 25-34***

Claims 25-34, among other claims, are also pending in application no. 10/810,185, which is a continuation of the application that is the subject of this response. They were added to the claims of this application in the Office Action response filed on August 15, 2005 to consolidate them in a single application. The Examiner has withdrawn these claims as allegedly being directed to an invention independent from the invention originally claimed. Specifically, the Office Action states that the added claims are directed to “a method of treating an individual in need of treatment for a capsaicin-responsive condition, which includes various kinds of treatments that respond to capsaicin, other than those already examined in the instant application.”

Applicants respectfully remind the Examiner that these claims were added to obviate an obviousness-type double patenting rejection to claims of application no. 10/810,185. Thus, the reasoning provided to conclude that the invention of claims 25-34 is now independent appears contradictory to that provided for the double patenting rejection. Given this contradiction, Applicants respectfully request that the Examiner include claims 25-34 into the pending claim set.

***Claim Rejections Under 35 U.S.C. § 103(a)***

Claims 1-24 and 34-44 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over US 5,856,361 in view of Wholehealthmd (data sheet). Particularly, the Office Action states that “irrespective of the solubility of capsaicin in hot or warm water, one of ordinary

skill in the art would have understood to remove the residual capsaicin from skin, after applying a capsaicin-containing composition to alleviate pain or any other condition capsaicin treats.”

Applicants respectfully traverse this rejection.

Specifically, Applicants disagree that the solubility of capsaicin in the cleansing composition should be disregarded. Applicants respectfully remind the Examiner that “To establish a *prima facie* case of obviousness, three basic criteria must be met, one of which is that when combined, the cited references must teach or suggest all the claim limitations.” See MPEP 2143.

Independent claims 1, 16, 17, 23, and 24 have been amended to recite a substance in which the capsaicin or capsaicin analog has a solubility of at least about 10 percent w/w. Support for this amendment is found, among other places, in originally filed claim 2 and in paragraphs [0008], [0011], [0012], [0015], [0022], [0038], [0044], [0053], and [0055]. Independent claim 34 already includes a composition in which capsaicin has a solubility of at least 10 percent by weight.

Holt does not describe a substance or composition which is separate from the capsaicin-containing composition in which capsaicin is soluble to at least about 10 percent by weight, as required by the claims. The data sheet describes water as a cleansing composition, but does not address the solubility of capsaicin in water or capsaicin solubility in any substance or composition for that matter. Applicants have obtained data regarding the solubility of capsaicin in water, at the Examiner’s request (see, Office Action response and Interview Summary dated November 9, 2005). The data shows that capsaicin is insoluble (less than 0.1% w/w) in soapy water at three different concentrations of antibacterial handsoap, even with frequent sonication over a 20 minute timeframe. Furthermore, according to the current USP classification (United States Pharmacopoeia, National Formulary, General Notices, page 9, USP28/NF23, January 1, 2005), capsaicin is considered to be insoluble at all three soap concentrations tested. Accordingly, the teachings of the wholehealthmd data sheet DO NOT cure the defect in Holt.

In view of the foregoing, applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a).

**CONCLUSION**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 524522000500. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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